

AMENDMENTS TO THE DRAWINGS

Applicants have attached a drawing sheet including amended Figure 3. As requested by the Examiner, Applicants have added reference number 500 to Figure 3. No new matter has been added. Applicants respectfully request entry of the enclosed drawing sheet.

Attachment: Replacement Sheet

REMARKS/ARGUMENTS

STATUS OF THE CLAIMS

Claims 1-10 are pending. Applicants have amended Claims 1 and 3-5. Applicants respectfully request reconsideration of pending Claims 1-10 in light of the following remarks.

OBJECTIONS TO THE SPECIFICATION

As requested by the Examiner, Applicants have amended Figure 3 to include reference numeral 500, as disclosed in the specification on page 24 at line 23. The amended drawing is attached as "Replacement Sheet." Applicants respectfully request removal of the objection to the specification.

The Examiner has also requested that Applicants update the biographical data sheet so that it is consistent with the priority claimed in the first paragraph of the specification. Applicants note that the priority claimed in the first paragraph of the specification is correct, and as a result, Applicants have perfected the priority claim. Applicants respectfully request further clarification from the Examiner regarding whether the filing receipt should be corrected or whether a new application data sheet should be filed.

INFORMATION DISCLOSURE STATEMENT

Applicants have submitted herewith the additional materials requested by the Examiner for the information disclosure statement, including copies of the references that were provided by Applicants but were not received by the Examiner, English abstracts for some of the non-English references, and a statement of relevance for one of the non-English references. Applicants respectfully request consideration of the additional materials submitted herewith and reconsideration of the Information Disclosure Statement.

DOUBLE PATENTING REJECTION

Claims 1, 2, and 7

Claims 1, 2, and 7 stand rejected under nonstatutory obviousness-type double patenting as being unpatentable over Claims 17 and 19 of U.S. Patent No. 6,449,507 (“the ‘507 Patent”).

Regarding drug delivery during a medical procedure, amended Claim 1 of the current application specifies “delivering a vasodilator substance directly to at least one specific vessel” and “delivering a vasoconstrictor substance directly to the at least one specific vessel.” Claim 17 of the ‘507 Patent merely specifies “drug delivery means for delivering at least one drug during the medical procedure.” The drug delivery means recited in Claim 17 of the ‘507 Patent does not make obvious the two method steps of amended Claim 1, including delivering a vasodilator and a vasoconstrictor directly to a specific vessel. Also, Claim 17 of the ‘507 Patent is directed toward an apparatus including drug delivery means, while amended Claim 1 of the current application is directed toward a method including delivering a vasodilator and a vasoconstrictor.

Dependent Claim 19 of the ‘507 Patent specifies several different drugs that can be delivered by the drug delivery means of independent Claim 17, including at least one vasoconstrictor (*e.g.*, epinephrine). However, the combination of independent Claim 17 and dependent Claim 19 of the ‘507 Patent does not make obvious amended Claim 1 of the current application. Neither Claim 17 nor Claim 19 of the ‘507 Patent specifies delivering a vasodilator, as specified by amended Claim 1. Also, neither Claim 17 nor Claim 19 specifies delivering a vasodilator or a vasoconstrictor directly to a specific vessel, as specified by amended Claim 1.

Claims 2 and 7 of the current application depend from Claim 1 and thus are not obvious in view of Claims 17 and 19 of the ‘507 Patent for the same reasons discussed above with respect to amended Claim 1. Accordingly, Applicants respectfully request reconsideration of the nonstatutory obviousness-type double patenting rejection of Claims 1, 2, and 7 in view of Claims 17 and 19 of the ‘507 Patent.

Claims 1, 2, 8, and 10

Claims 1, 2, 8, and 10 stand rejected under nonstatutory obviousness-type double patenting as being unpatentable over Claims 17, 20, and 28 of U.S. Patent No. 6,718,208 (“the ‘208 Patent”).

Regarding drug delivery during a medical procedure, amended Claim 1 of the current application specifies “delivering a vasodilator substance directly to at least one specific vessel” and “delivering a vasoconstrictor substance directly to the at least one specific vessel.” Claim 17 of the ‘208 Patent merely specifies “drug delivery means for delivering at least one drug during the medical procedure.” The drug delivery means recited in Claim 17 of the ‘208 Patent does not make obvious the two method steps of amended Claim 1, including delivering a vasodilator and a vasoconstrictor directly to a specific vessel. Also, Claim 17 of the ‘208 Patent is directed toward an apparatus including drug delivery means, while amended Claim 1 of the current application is directed toward a method including the steps of delivering a vasodilator and a vasoconstrictor.

Dependent Claim 20 of the ‘208 Patent specifies different nerves to stimulate with the nerve stimulator of independent Claim 17 of the ‘208 Patent. Dependent Claim 28 of the ‘208 Patent specifies different medical procedures that can be performed using the nerve stimulator of independent Claim 17 of the ‘208 Patent. Neither Claim 20 nor Claim 28 of the ‘208 Patent specifies any type of vasodilator or vasoconstrictor substance delivered by the drug delivery means or where the drugs are delivered.

Claims 2, 8, and 10 of the current application depend from Claim 1 and thus are not obvious in view of Claims 17, 20, and 28 of the ‘208 Patent for the same reasons discussed above with respect to amended Claim 1. Accordingly, Applicants respectfully request reconsideration of the nonstatutory obviousness-type double patenting rejection of Claims 1, 2, 8, and 10 in view of Claims 17, 20, and 28 of the ‘208 Patent.

CLAIM REJECTION – 35 U.S.C. § 102

Independent Claim 1

Claim 1 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,414,018 issued to Duhaylongsod (hereinafter “Duhaylongsod”).

Claim 1 specifies “delivering a vasodilator substance directly to at least one specific vessel while the beating of the heart is in the first condition” and “delivering a vasoconstrictor substance directly to the at least one specific vessel.”

Duhaylongsod discloses compositions and methods to induce ventricular asystole in a patient prior to a surgical procedure. *Duhaylongsod*, col. 11, lines 37-39. Duhaylongsod also discloses that “the use of a cholinergic agent, such as carbachol, in combination with a β -blocker, such as propranolol, preferably produces ventricular asystole at significantly reduced dosages of the cholinergic agent.” *Id.* at col. 16, lines 20-23. Duhaylongsod further discloses the following:

A dosage amount of phenylephrine in the range of about 0.1 to 1.0 mg if needed may be administered to counteract any hypotension effects associated with carbachol administration. Additionally, nitroglycerine may be required in some patients to counteract the coronary vasodilator effects of systemic phenylephrine administration.

Id. at col. 18, lines 6-12 (emphasis added).

If the phenylephrine of Duhaylongsod is the “vasodilator” of Claim 1 and the nitroglycerine of Duhaylongsod is the “vasoconstrictor” of Claim 1, Duhaylongsod does not disclose administering the phenylephrine and the nitroglycerin directly to a specific vessel. Duhaylongsod only discloses systemically administering phenylephrine to a patient if the patient experiences hypotension due to the carbachol. Furthermore, Duhaylongsod only discloses administering nitroglycerin to the patient in response to the coronary vasodilator side-effects of phenylephrine. Duhaylongsod does not disclose that phenylephrine and nitroglycerine are delivered directly to a specific vessel, but rather only systemically to counteract side-effects in some patients.

Accordingly, Duhaylongsod does not disclose “delivering a vasodilator substance directly to at least one specific vessel while the beating of the heart is in the first condition” and “delivering a vasoconstrictor substance directly to the at least one specific vessel,” as specified by amended Claim 1. Therefore, independent Claim 1 and dependent Claims 2-10 are allowable.

Dependent Claims 2-4 and 6-10

Claims 2-4 and 6-10 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Duhaylongsod. Claims 2-4 and 6-10 depend from Claim 1 and are therefore allowable for the reasons discussed with respect to Claim 1. Claims 2-4 and 6-10 also specify additional patentable subject matter not specifically discussed herein.

CLAIM REJECTION – 35 U.S.C. § 103

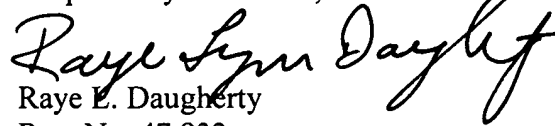
Dependent Claim 5

Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Duhaylongsod in view of U.S. Patent No. 5,153,178 issued to Maroko. Claim 5 depends from Claim 1 and is therefore allowable for the reasons discussed with respect to Claim 1. Claim 5 also specifies additional patentable subject matter not specifically discussed herein.

CONCLUSION

In light of the above, Applicant respectfully requests reconsideration and allowance of pending Claims 1-10.

Respectfully submitted,


Raye E. Daugherty
Reg. No. 47,933

File No. 065071-9060-02
Michael Best & Friedrich LLP
100 East Wisconsin Avenue, Suite 3300
Milwaukee, Wisconsin 53202-4108
414.271.6560